IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

DENISE MCLEOD, individually and as Personal Representative of the Estate of CATHERINE WEBB, deceased,	CASE NO._____
Plaintiff, **v.**	**COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL**
NORTHSTAR RX LLC, a Delaware corporation; and MCKESSON CORPORATION, d/b/a NORTHSTAR RX LLC, a Delaware corporation	
Defendant.	

DENISE MCLEOD, individually and as Personal Representative of the Estate of CATHERINE WEBB, deceased, by and through the undersigned attorney, states and alleges as follows:

I. PARTIES

1. DENISE MCLEOD, is an individual of the full age of majority who is a resident and citizen of Rockingham County, North Carolina. Contemporaneous with the filing of this complaint, DENISE MCLEOD is pursing Letters of Administration in her name in furtherance of pursuing civil claims on behalf of the Estate of CATHERINE WEBB, herself and all other interested heirs and beneficiaries who have the right to pursue the same against Defendants for injuries and the wrongful death of CATHERINE WEBB (hereinafter referred to as "Plaintiff"). Plaintiff, deceased, CATHERINE WEBB, was an African-American individual of the full age of majority who was a resident and citizen of Rockingham County, North

Carolina.

2. Plaintiff brings this action for the purpose of recovering all damages allowable by law for personal injuries she suffered as a result the ingestion of a pharmaceutical drug, ALLOPURINOL, manufactured by Defendants.

3. Defendant NORTHSTAR RX, LLC, (hereinafter referred to as "NORTHSTAR") is a Delaware corporation with its headquarters and principal place of business in Memphis, Tennessee. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of the ALLOPURIONOL detailed below. Plaintiff is informed and believes Defendant manufactured the ALLOPURIONOL that was dispensed to Plaintiff.

4. Defendant MCKESSON CORPORATION, d/b/a NORTHSTAR Rx LLC (hereinafter referred to as "MCKESSON") is a Delaware corporation with a principal place of business in California. Plaintiff(s) allege that Defendant Northstar Rx LLC is the wholly owned subsidiary of Defendant McKesson Corporation. Defendant was involved in the manufacture, distribution, marketing, sale, labeling, and design of the ALLOPURINOL detailed below. Plaintiff is informed and believes Defendant distributed the ALLOPURINOL that was dispensed to Plaintiff.

5. Defendants NORTHSTAR and MCKESSON shall be collectively referred to herein as "Defendant" or "Drug Company Defendants".

6. At all times material hereto, Defendant was engaged in the business of testing, developing, manufacturing, labeling, marketing, distributing, promoting and/or selling, either directly or indirectly, through third parties, as successor in interest,

or other related entities, ALLOPURINOL in the State of North Carolina and in interstate commerce.

7. At all relevant times, Defendant was acting by and through its agents, servants and/or employees, each of whom were acting within the scope and course of their employment by agency or authority on their behalf.

8. At all times relevant hereto, Defendant was in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising the pharmaceutical drugs known and/or branded as ALLOPURINOL and/or the generic equivalent, (hereinafter referred to as "ALLOPURINOL" or "the drug") and transacted business throughout interstate commerce, including in the State of North Carolina and specifically, this county.

9. At all relevant times, Defendant did manufacture, create, design, assemble, test, label, sterilize, package, distribute, promote, supply, market, sell, advertise, and/or otherwise distribute in the State of North Carolina and in interstate commerce ALLOPURINOL tablets.

10. At all relevant times, Defendant sold, delivered and/or distributed such products for ultimate sale and/or use interstate commerce within the United States and the State of North Carolina and this district by consumers, including Plaintiff.

II.

JURISDICTION AND VENUE

11. Jurisdiction exists as against the defendant, NORTHSTAR RX, LLC in that the Plaintiff was a citizen and resident of Rockingham County, North Carolina; the

Defendants, NORTHSTAR RX, LLC, is incorporated in Tennessee; which said Defendants transacted substantial business in this county.

12. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over the Defendant, because Defendant is present in this state such that requiring an appearance does not offend traditional notions of fair play and substantial justice. This Court has personal jurisdiction over the Defendant, pursuant to, and consistent with, the Constitutional requirements of Due Process in that the Defendant acting through agents or apparent agents, committed one or more of the following: (1) Defendant transacted business in this state; (2) Defendant owned, used or possessed real estate situated in this state; (3) Defendant made or performed a contract or promise substantially connected within this state; (4) Defendant does business in and within this state; and; (5) Requiring Defendant to litigate this claim in this state does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution; and (6) Defendant marketed, promoted, and sold ALLOPURINOL drug products concerned in this litigation in this district and throughout the United States. Accordingly venue is proper.

III.

STATEMENT OF FACTS

13. This case involves the pharmaceutical prescription drug ALLOPURINOL, which is commonly prescribed to treat gout.

14. ALLOPURINOL'S principal label, known as the "Package Insert" was developed

by the Defendant and accompanied all prescription drug products and/or samples. By state and federal law, the labeling is to include accurate information concerning a drug's active and inactive ingredients, clinical pharmacology, indications, usage, contraindications, warnings, precautions and side effects.

15. Defendant failed to fully, truthfully and accurately communicate the risks of ALLOPURINOL, and as a result misled the medical community, physicians, Plaintiff's physician and Plaintiff about the risks of severe cutaneous side effects, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TENS) associated with the use of ALLOPURINOL.

16. Defendant caused its Package Insert to be disseminated to Plaintiff's Physicians and other members of the medical community. Defendant's Package Insert minimized the risk of a severe cutaneous reactions and severe side effects described herein, including but not limited to Stevens Johnson Syndrome in patients ingesting ALLOPURINOL, despite available literature that Defendant should have found and reported stating a statistically significant higher risk for such reactions.[1]

17. Defendant minimized the risk of SJS and TENS and failed to fully, truthfully and accurately communicate the risks associated with ALLOPURINOL, despite available literature associating severe cutaneous reactions, including, SJS and TENS with the use of ALLOPURINOL, and as a result misled the medical community, physicians, Plaintiff's physician and Plaintiff about the risks of

[1] Roujeau, *et al.*, Severe Adverse Cutaneous Reactions to Drugs, *New England Journal of Medicine*, Vol. 331: 1272-1285, Nov. 1994; Roujeau, *et al.*, Medication Use and the Risk of Stevens-Johnson Syndrome or Toxic Epidermal Necrolysis, *New England Journal of Medicine*, Vol. 333: 1600-1608, Dec. 1995.

severe side effects described herein, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TENS) associated with the use of ALLOPURINOL.

18. Furthermore, since 2003, Defendant knew or should have known that certain ethnic and racial groups were predisposed to having risk factors to injury due to, among other things, a variation in metabolism rates for pharmaceutical agents. Defendant knew or should have known that ALLOPURINOL was linked to SJS/TENS based on genetic markers. The specificity of these associations became common knowledge to companies including Defendant, which are held to the highest of standards as specialists in those fields of science, which relate to the design, testing, use and risks associated with pharmaceutical drugs. Again, in 2005, Defendant had knowledge that it should undertake reasonable efforts to perform post-marketing risk analysis regarding ALLOPURINOL. In fact, Defendant did nothing including failing to initiate any study regarding the pharmacogenetic relationship between its drug ALLOPURINOL and the increased incidence of cutaneous reactions, including, SJS/TENS among persons with specific alleles and/or polymorphisms.

19. Despite Defendant's knowledge and awareness of the need to account for these associations, however, Defendant did nothing to identify the potential risk of a certain segment of the population to SJS/TEN from ingesting ALLOPURINOL.

20. In September 2009, it was reported that a study conducted in Taiwan found an association between HLA-B*5801 allele and ALLOPURINOL induced Stevens-Johnson syndrome (SJS) in certain populations.

21. Defendant revised its label on or about December 2005, and failed to add any information or warning regarding the true risk and association between ALLOPURINOL and cutaneous reactions, including SJS/TENS and failed to add any information or warning regarding the predisposition of certain populations and females to SJS/TENS from the use of its drug.

22. Defendant failed to update its label from the period of 2005 to present to add any information or warning regarding the predisposition of certain populations and females to SJS/TENS from the use of its drug.

23. Defendant failed to undertake its duty of conducting post-marketing surveillance and studies in the face of a clear connection between its drug and SJS/TENS.

24. On or after Plaintiff's ingestion of Defendant's drug, the Defendant continued to minimize the risk of SJS and TENS in its ALLOPURINOL label and failed to fully, truthfully and accurately communicate the risks associated with ALLOPURINOL, despite available literature that the incidence of SJS and TENS was higher than the label indicated, and as a result mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the risks of severe side effects described herein, including but not limited to Stevens Johnson Syndrome (SJS) and Toxic epidermal necrolysis (TENS) associated with the use of ALLOPURINOL.

25. Defendant aggressively promoted ALLOPURINOL to physicians for use in patients, such as Plaintiff, through medical journal advertisements, use of mass mailings, and direct communications from the Defendant sales force, as well as other promotional materials including package inserts, physician desk reference,

monographs and patient brochures as these materials downplayed the significance of the adverse effects of ALLOPURINOL and the risk of Stevens-Johnson Syndrome and severe cutaneous reactions.

26. Defendant knew there was substantial and mounting evidence of the enormous risk of serious systemic reactions such as hypersensitivity syndrome, SJS/TENS associated with this drug. Yet, despite the scientific and epidemiological evidence that would compel Defendant to issue warnings to physicians and patients, Defendant consciously decided to ignore this pertinent information when it came time to protect the health of patients in the United States from the severe cutaneous adverse events associated with this drug.[2]

27. Despite accounts of severe cutaneous reactions and severe side effects as described herein including but not limited to SJS/TENS reported directly to the Defendant, and reports in the literature, the Defendant failed to report the true and accurate risk of said side effects to the Plaintiff's physicians and the medical community and regularly represented in its advertising and promotional messages to said individuals that the risks of cutaneous adverse reactions associated with exposure to this drug was minimal when in fact it was significantly greater.

28. The ALLOPURINOL manufactured and/or supplied by Defendant was defective due to inadequate pre-marketing and post-marketing warnings or instructions because, after Defendant knew or should have known of the risk of injury from ALLOPURINOL, Defendant failed to provide adequate warnings to Plaintiff's

[2] Mockenhaupt, *et al.*, Stevens-Johnson Syndrome and Toxic Epidermal Necrolysis: Assessment of Medication Risk with Emphasis on Recently Marketed Drugs. The EuroScar-Study, *Journal of Investigative Dermatology* (2008), 128, 35-44.

physicians, Plaintiff, physicians and the medical community who prescribed the drug, and to their patients who were the ultimate consumers of the product. Yet despite their inadequate post-marketing warnings and instructions to said persons Defendant continued to aggressively promote the product thereby making Drug Company Defendants strictly liable for failure to warn.

29. On or about February 24, 2009, Plaintiff's physician, Dr. Roger Travis, prescribed ALLOPURINOL tablets to Plaintiff for treatment of gout.

30. Plaintiff's pharmacy, Wal-Mart in Reidsville, North Carolina specifically filled her Allopurinol tablets with Defendants' product.

31. Thereafter, Plaintiff ingested Defendants' ALLOPURINOL as prescribed.

32. On or after March 3, 2009, as a result of her ingestion of ALLOPURINOL, Plaintiff developed rashing, and thereafter was presented to UNC Chapel Hill Hospital at 101 Manning Drive, Chapel Hill, North Carolina for medical treatment and was admitted to UNC Chapel Hill Hospital on March 3, 2009, due to symptoms caused by Allopurinol.

33. Plaintiff died on March 8, 2009.

34. Upon information and belief, in prescribing the ALLOPURINOL, drug to Plaintiff, Plaintiff's physicians relied upon information published in the package inserts and/or the Physician's Desk Reference (hereinafter "PDR"); materials and/or labeling otherwise disseminated by the Defendant.

35. Under the FDA schema, Defendant manufactures, sells, markets and distributes ALLOPURINOL, which was ingested by Plaintiff herein.

36. Plaintiff's ingestion of Defendant's ALLOPURINOL caused her injuries.

37. Plaintiff's physicians were not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated by Defendant.

38. Defendant provided misleading information about the true risks associated with the use of Defendant's ALLOPURINOL to the medical community, Plaintiff's Physician, and Plaintiff (and other foreseeable users similarly situated), particularly with respect to females and certain ethnic groups, including Plaintiff.

39. Plaintiff used Defendant's pharmaceutical drug ALLOPURINOL without substantial change in condition of the drug between the time of design and manufacture of the drug and the time Plaintiff used the drug as directed.

40. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of the Defendant 's dissemination of inaccurate, misleading, materially incomplete, false, and otherwise inadequate information concerning the potential effects of exposure to Defendant's ALLOPURINOL and the ingestion of ALLOPURINOL to the medical community, physicians, Plaintiff's physician of the drug.

41. Plaintiff has experienced and will continue to experience medical and related expenses, loss of ability to provide household services, disfigurement, disability, pain and suffering, psychological injury and other injuries and damages due to the injuries he suffered caused by the ingestion of Defendant's ALLOPURINOL.

IV. ALLEGATIONS

42. At all relevant times hereto, Defendant did not investigate the accuracy of its' ALLOPURINOL drug label.

43. Defendant were negligent in failing to report published articles and overwhelming scientific evidence of increased risks of severe side effects described herein including SJS/TEN associated with ALLOPURINOL therapy to the FDA, healthcare providers or patients in the U.S. The regulations required them to report these papers, undertake action to add new warnings to the package insert for ALLOPURINOL, and to report any foreign regulatory actions that included new warnings or new safety information for the product.

44. At all relevant times hereto, Defendant did not review the medical literature for its' ALLOPURINOL drug product even though it had a duty to review said literature.

45. Defendant are under a duty to ensure that its' ALLOPURINOL label is accurate.

46. Under the Code of Federal Regulations, Defendant had a duty to ensure its ALLOPURINOL warnings to the medical community were accurate and adequate; had a duty to conduct post market safety surveillance; to review all adverse drug event information (ADE), and to report any information bearing on the risk and/or prevalence of side effects caused by ALLOPURINOL, the medical community, Plaintiff's physician and Plaintiff.

47. Under the Code of Federal Regulations, if Defendant discovers information in the course of the fulfillment of its duties as outlined above, Defendant must report that information to the medical community, Plaintiff's physician and Plaintiff ALLOPURINOL to ensure that its warnings are continually accurate and adequate.

48. Defendant breached its duty to the medical community, Plaintiff's Physician,

Plaintiff, and other foreseeable users similarly situated because it failed to ALLOPURINOL warnings to the medical community, Plaintiff's physician, Plaintiff, other foreseeable users similarly situated were accurate and adequate.

49. Defendant breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to conduct post market safety surveillance of ALLOPURINOL, and failed to report any significant data regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of ALLOPURINOL.

50. Defendant breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to review all adverse drug event information (ADE), and to report any information bearing upon the adequacy and/or accuracy of its warnings, efficacy, or safety, including the risks and/or prevalence of side effects caused by ALLOPURINOL, the medical community, Plaintiff's physician and Plaintiff.

51. Defendant breached its duty to the medical community, Plaintiff's physician, Plaintiff, and other foreseeable users similarly situated because it failed to periodically review all medical literature and failed to report any significant data concerning severe side effects as described herein, including but not limited to SJS and TENS, *regardless of the degree of significance*, regarding the adequacy and/or accuracy of its warnings, efficacy, or safety of ALLOPURINOL.

52. If a drug company learns of side effects, risks or misleading and inaccurate information in the ALLOPURINOL label, it must request and/or submit labeling revision for the drug, under the FDA schema.

53. Defendant knew or should have known about the side effects, risks, misleading and inaccurate information contained in its ALLOPURINOL label and knowingly and intentionally withheld that information and or failed to report that information to the medical community, physicians, Plaintiff's physicians and Plaintiff.

54. At all times material hereto, Defendant were aware of the serious side effects caused by ALLOPURINOL including, but not limited to, severe side effects described herein and failed to fulfill its obligation to report and divulge said side effects, and in doing so, mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the safety of the use of the drug.

55. At all times material hereto, Defendant knew or should have known that physicians were **not** aware of or did not fully appreciate the seriousness of the risks associated with use of ALLOPURINOL.

56. Defendant knew or should have known that the package insert use mass mailing language promulgated and distributed. Defendant did not adequately inform physicians about the risks of severe side effects described herein, and/or SJS or TENS associated with ALLOPURINOL; yet, said Defendant failed to communicate said information to the medical community, Plaintiff's physicians, Plaintiff or other foreseeable users alike, and in doing so, mislead the medical community, physicians, Plaintiff's physician and Plaintiff about the safety of the use of this drug.

57. Defendant knew, or should have known through the exercise of reasonable care, that the labeling for ALLOPURINOL substantially understated the prevalence of the risk of severe cutaneous side effects described herein, including SJS and

TENS associated with ALLOPURINOL.

58. Defendant failed to disclose and communicate material safety information regarding the risks of this drug to the medical community, Plaintiff's physician and Plaintiff, knowing that such failure would result in serious injury to patients who were prescribed ALLOPURINOL by a physician who was not aware of the risk of severe skin reactions, SJS and TENS.

59. Defendant misrepresented to physicians, Plaintiff physicians, and to foreseeable users, including Plaintiff that ALLOPURINOL was safe to use and that permanent and severe side effects described herein, SJS and TENS were rare and/or infrequent.

60. Defendant did not disclose or warn physicians about the actual prevalence of known side effects of ALLOPURINOL when ALLOPURINOL is used as marketed by Defendant, or when used in Plaintiff, a foreseeable patient.

61. At the time Defendant made the above-described representations, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true.

62. Plaintiff's serious and permanent injuries, as described above, came about as a foreseeable and proximate result of Defendant's failure to correct false and misleading information it disseminated to physicians, which contained inaccurate, misleading, materially incomplete, false and otherwise inadequate information concerning the efficacy, safety and potential side effects of ALLOPURINOL.

63. As a proximate result of the misrepresentation of Defendant, Plaintiff sustained the injuries and damages as described in this Complaint.

64. Defendant had an absolute duty to disclose the true facts regarding the safety of ALLOPURINOL to the medical community, to physicians and their patients, pharmacists, and the generic ALLOPURINOL industry, which it negligently and/or intentionally failed to do.

65. Defendant had a duty to ensure that it had a reasonable basis for making the representations regarding the safety, efficacy, risks and benefits of ALLOPURINOL, were accurate and was under at duty to exercise reasonable care in making those representations, to accurately make those representations, and to not make misrepresentations, all of which it negligently and/or intentionally failed to do.

66. Plaintiff would not have suffered Plaintiff's injuries but for the above misrepresentations or omissions of Drug Company Defendants.

67. Defendant's misrepresentations or omissions were a cause in fact and a proximate cause of Plaintiff's damages.

68. At all times mentioned in this Complaint, the Defendant had a duty to truthfully, accurately and fully disclose information and data which would reflect that the risks of severe skin reactions, SJS and TENS clearly outweighed the utility of the ALLOPURINOL or its therapeutic benefits to patients.

69. The Defendant was negligent, and breached its duties owed to the medical community, Physicians, Plaintiff's physician and Plaintiff, with respect to ALLOPURINOL in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that ALLOPURINOL was frequently prescribed for the use of Plaintiff and other consumers of the drug, Defendant failed to accompany the ALLOPURINOL with adequate warnings and instructions regarding the adverse side effects associated with the use of

ALLOPURINOL; and

Defendant failed to perform adequate testing on ALLOPURINOL; and

(c) Despite knowledge of hazards, Defendant failed to conduct adequate post-marketing surveillance to determine the safety of the ALLOPURINOL; and

(d) Despite knowledge of hazards, Defendant failed to adequately warn Plaintiff's physicians or Plaintiff that the use of ALLOPURINOL could result in serious side effects, including severe skin reactions, SJS and TENS; and

(e) Despite the fact that the Defendant knew or should have known that ALLOPURINOL caused unreasonably dangerous side effects, Defendant failed to adequately disclose the known or knowable risks associated with ALLOPURINOL and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

(f) Despite the fact that the Defendant knew or should have known that ALLOPURINOL caused an unreasonable an increase risk of severe skin reactions and Defendant failed to adequately disclose the known or knowable risks associated with ALLOPURINOL and willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff's safety or welfare.

70. As a result of the negligence of the Defendant, ALLOPURINOL was prescribed to Plaintiff for her use; and was used as prescribed; thereby, causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this complaint.

71. The negligence of the Defendant was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer.

72. At all times mentioned in this Complaint, ALLOPURINOL was defective and/or unreasonably dangerous to Plaintiff at the time it left the control of the Defendant.

73. ALLOPURINOL was "defective" and "unreasonably dangerous" when the drug was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:

(a) At the time ALLOPURINOL left the control of the Defendant it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the ALLOPURINOL breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff's physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seek recovery herein.

(b) ALLOPURINOL was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time ALLOPURINOL left the possession of the Defendant, and that such risks clearly outweighed the utility of ALLOPURINOL or its therapeutic benefits.

(c) At the time ALLOPURINOL left the control of the Defendant the drug possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the ALLOPURINOL left the possession of the Defendant. Specifically, although the Defendant was well aware that ALLOPURINOL could potentially cause severe side effects described herein, SJS and TENS, warnings of such adverse health conditions were either not included on the package insert for ALLOPURINOL and/or the warnings were inadequate to inform reasonably prudent physicians and foreseeable users of the risks. The Defendant failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of ALLOPURINOL.

(d) The Defendant's warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the ALLOPURINOL taking into account the characteristics of the ALLOPURINOL, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases ALLOPURINOL, such as the Plaintiff.

(e) The ALLOPURINOL manufactured and supplied by the Defendant was further defective due to inadequate post-marketing warning or instruction because, after the Defendant knew or should have known of the risks of injury from ALLOPURINOL associated with the use as commonly prescribed, Defendant failed to promptly respond to and adequately warn about severe skin reactions, SJS and TENS to foreseeable users.

(f) The ALLOPURINOL manufactured and supplied by the Defendant was further defective due to inadequate post-marketing warning or instruction because, after the Defendant knew or should have known of the risks of injury from ALLOPURINOL associated with the use as commonly prescribed, Defendant

failed to promptly respond to and adequately warn about an increased risk as reported in the medical literature for severe skin reactions, SJS and TENS posed to patients, who were foreseeable users of the drug.

74. The Defendant knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery.

75. A reasonably competent physician who prescribed ALLOPURINOL and a reasonably competent Plaintiff who consumed ALLOPURINOL would not realize its dangerous condition.

76. The reasonably foreseeable use of ALLOPURINOL involved substantial dangers not readily recognizable by Plaintiff's physician, who acted as an ordinary reasonable and prudent physicians would, when prescribing ALLOPURINOL to an ordinary, reasonable and prudent patient, like Plaintiff.

77. The Defendant knew that ALLOPURINOL which was to be prescribed by physicians and used by foreseeable users without inspection for defects in ALLOPURINOL or in any of its components or ingredients and that ALLOPURINOL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

78. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time of the use of ALLOPURINOL, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

79. These defects caused serious injuries to Plaintiff when the ALLOPURINOL was used in its intended and foreseeable manner, and in the manner recommended by

the Defendant or in a non-intended manner that was reasonably foreseeable.

80. Defendant knew that its warranties regarding safety for the use, would be relied upon by ordinary, reasonable and prudent physicians who would share that information with other physicians in their community and that eventually physicians would come to rely on Defendant's express warranties concerning the safety of ALLOPURINOL.

81. Defendant's express warranties about the safety of ALLOPURINOL were false and intentionally and/or negligently misleading.

82. Defendant also knew that the risks of potentially severe side effects described herein, including SJS and TENS when ALLOPURINOL is used were much greater than most physicians realized. By failing to give adequate warnings about the properties of ALLOPURINOL and the risk of the use that is associated with those properties, the Defendant breached implied warranties of merchantability and fitness for the ordinary use of ALLOPURINOL.

83. At all times mentioned in this Complaint, the Defendant manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied and sold ALLOPURINOL and prior to the time it was used by Plaintiff, the Defendant impliedly warranted to Plaintiff and to Plaintiff physicians that the ALLOPURINOL was of merchantable quality and safe and fit for the use for which it was intended.

84. Plaintiff relied on the skill and judgment of the Defendant in using ALLOPURINOL as prescribed.

85. ALLOPURINOL was unsafe and unfit for its intended use; was not of

merchantable quality, as warranted by the Defendant, in that it had very dangerous propensities when put to its intended use and would cause severe injury to the user. ALLOPURINOL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution. As a result, the drug proximately caused Plaintiff to sustain damages and injuries as alleged in this Complaint.

86. By virtue of Defendant's acts and omissions, Drug Company Defendants are liable to Plaintiff because Defendant's acts and omissions have proximately caused Plaintiff to suffer permanent injuries.

87. Plaintiff used ALLOPURINOL, which was provided to her, respectively, in a condition that was substantially the same as the condition in which it was manufactured and sold.

88. As a result of Defendant's actions, Plaintiff and her prescribing physicians were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified in this complaint, and that those risks were the direct and proximate result of Defendant's acts, omissions, and misrepresentations.

89. As a direct and proximate result of Defendant, the Plaintiff was prevented from pursuing her normal activities and employment, has experienced severe pain and suffering and mental anguish, and has been deprived of her ordinary pursuits and enjoyments of life.

90. Equity dictates that this Court provide the Plaintiff a remedy that provides

Plaintiff with sufficient information and medical monitoring appropriate for Plaintiff to make informed decisions related to Plaintiff's physical well-being. Absent such notice Plaintiff will be irreparably harmed.

91. Plaintiff is also entitled to any procedural protections deemed necessary and appropriate to protect Plaintiff's legal interests.

92. Plaintiff is entitled to recovery an award for the injuries caused by the Defendant. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff ingested ALLOPURINOL, which was causally related to and contributed to Plaintiff's severe skin reaction and injuries resulting from the adverse reaction caused by Defendant's drug.

93. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff has suffered extreme emotional distress, anguish, physical and mental suffering, and is rendered physically disabled.

94. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff experienced extreme embarrassment, shame, anguish, anxiety, and has sustained a loss of enjoyment of life.

95. Plaintiff seeks the recovery for past and future special damages, which includes medication, doctor, rehabilitation, therapy, and other assisted living, nursing care and loss of earning capacity. Plaintiff also seeks damages in the amount to be determined for the wrongful conduct of the Defendant.

96. As a direct and proximate result of the aforesaid acts of and/or omissions by the Defendant, Plaintiff, has:

(a) Suffered severe and permanent injuries, which he will be forced to endure for the remainder of Plaintiff's life;

(b) Suffered physical impairment and disfigurement; and

(c) Suffered physical pain and suffering;

(d) Suffered mental pain and suffering;

(e) Suffered from loss of enjoyment of life;

(f) Incurred and will continue to incur various sums of money for past, present and future medical expenses associated with monitoring and treating Plaintiff injuries; and

(g) Incurred attorney's fees and expenses of litigation related to this action.

IV.

WRONGFUL CONDUCT

COUNT 1

STRICT PRODUCTS LIABILITY

97. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

98. At all relevant times the Defendant was engaged in the business of manufacturing, designing, testing, marketing, promoting, distributing, and/or selling ALLOPURINOL.

99. Defendant developed, marketed and distributed ALLOPURINOL to the general public even after learning of the design and manufacturing defects that threatened the intended use of the drug.

100. Defendant's ALLOPURINOL was defective and unreasonably dangerous and was expected to and did reach Plaintiff without substantial change in the drug.

101. At all times mentioned in this Complaint, ALLOPURINOL was defective and/or unreasonably dangerous to Plaintiff at the time it left the control of the Defendant.

102. Defendant knew or should have known through testing, adverse event reporting, or otherwise, that the drug created a high risk of bodily injury and serious harm.

103. The dangerous propensities of ALLOPURINOL were known or scientifically knowable, through appropriate research and testing, to the Defendant at the time said Defendant distributed, supplied, or sold the drug, and not known to ordinary physicians who would be expected to prescribe the drug for their patients, or their patients.

104. ALLOPURINOL as distributed by the Defendant was defective and unreasonably dangerous inasmuch as the ALLOPURINOL was not accompanied by warnings and instructions that were appropriate and adequate to render the drugs reasonably safe for their ordinary, intended, and reasonably foreseeable uses, in particular the common, foreseeable, and intended use of the products for the ALLOPURINOL therapy.

105. Prior to the manufacturing, sale and distribution of said drug products, Defendant knew that its ALLOPURINOL was in a defective condition as previously described, and knew that those who were prescribed and took the same would experience, and did experience, severe physical, mental and emotional injuries.

106. Defendant had prior notice and knowledge from several sources, prior to the date of dispensing of said drug products to Plaintiff that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff, and as such said consumers of said drug were unreasonably subjected to risk of injury from the consumption of said drug.

107. Despite such knowledge, Defendant for the purpose of enhancing Defendant's

profits, knowingly and deliberately failed to warn the public, including Plaintiff, of the extreme risk of physical injury occasioned by said defects inherent in said drug. Defendant intentionally proceeded with the manufacturing, the sale and distribution, and marketing of the drug with knowledge that consumers would be exposed to serious danger in order to advance Defendant's own pecuniary interest.

108. ALLOPURINOL was "defective" and "unreasonably dangerous" when the product initially was patented, and subsequently when it was promoted and entered into the stream of commerce and was received by Plaintiff, in one or more of the following respects:

(a) At the time ALLOPURINOL left the control of the Defendant it was defective and unreasonably dangerous due to a failure to contain adequate warnings or instructions, or, in the alternative, because it was designed in a defective manner, or, in the alternative, because the product breached an express warranty or failed to conform to other expressed factual representations upon which Plaintiff physicians justifiably relied, or because it breached an implied warranty, all of which proximately caused the damages for which Plaintiff seeks recovery herein.

(b) ALLOPURINOL was not reasonably safe as designed, taking into account the foreseeable risks involved in its use at the time the product left the possession of the Defendant, and that such risks clearly outweighed the utility of the product or its therapeutic benefits.

(c) At the time ALLOPURINOL left the control of the Defendant it possessed a dangerous characteristic that may cause damage and it was not reasonably safe due to inadequate or defective warnings or instructions that were known or reasonably scientifically knowable at the time the product left the possession of the Defendant. Specifically, although the Defendant were well aware that ALLOPURINOL could potentially cause severe side effects described herein, SJS and TENS, and in fact, had significantly greater prevalence and severity of these side effects than revealed by the manufacturer; and/or warnings of such adverse health conditions were either not included on the package insert for these products or they were not adequate to inform reasonably prudent physicians and consumers. The Defendant failed to use reasonable care to provide an adequate warning of these dangerous characteristics to handlers and users of ALLOPURINOL.

(d) The Defendant's warnings or instructions were not of a nature that a reasonably prudent drug company in the same or similar circumstances would have provided

with respect to the danger. There were no warnings or instructions that communicate sufficient information on the dangers and safe use of the product taking into account the characteristics of the product, and/or the ordinary knowledge common to the physician who prescribes and the consumer who purchases the product, such as the Plaintiff.

(e) The ALLOPURINOL manufactured and supplied by the Defendant was further defective due to inadequate post-marketing warning or instruction because, after the Defendant knew or should have known of the risks of injury from ALLOPURINOL associated with the use as commonly prescribed, they failed to promptly respond to and adequately warn about severe side effects described herein, SJS and TENS.

109. The Defendant knew, or in light of reasonably available scientific knowledge should have known, about the danger that caused the injuries for which Plaintiff seeks recovery. A reasonably competent physician who prescribed ALLOPURINOL and a reasonably competent Plaintiff who consumed ALLOPURINOL would not realize its dangerous condition.

110. The Defendant knew or in light of reasonably available scientific knowledge should have known about the danger associated with use of ALLOPURINOL that caused the damages for which Plaintiff seeks recovery.

111. The reasonably foreseeable use of ALLOPURINOL involved substantial dangers not readily recognizable by the ordinary physician who prescribed ALLOPURINOL or the patient, like Plaintiff, who consumed ALLOPURINOL.

112. The Defendant knew that the ALLOPURINOL was to be prescribed by physicians and used by consumers without inspection for defects in the product or in any of its components or ingredients and that ALLOPURINOL was not properly prepared nor accompanied by adequate warnings of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

113. Plaintiff and Plaintiff's physicians did not know, nor had reason to know, at the time

of the use of ALLOPURINOL, or at any time prior to its use, of the existence of the above-described defects and inadequate warnings.

114. These defects caused serious injuries to Plaintiff when the product was used in its intended and foreseeable manner, and in the manner recommended by the Defendant and/or in a non-intended manner that was reasonably foreseeable.

WHEREFORE, Plaintiff prays for judgment against Defendant, in an amount, which will compensate the Plaintiff for her injuries.

COUNT 2

NEGLIGENCE

115. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

116. Defendant had a duty to exercise the care of an expert in all aspects of the formulation, manufacture, compounding, testing, inspection, packaging, labeling, distribution, marketing, and sale of ALLOPURINOL to ensure the safety of its drug and to ensure that the consuming public, including the Plaintiff and Plaintiff physicians and agents, obtained accurate information and instructions for the use of ALLOPURINOL.

117. As a direct and proximate cause of Defendant's conduct, Plaintiff has suffered and will continue to suffer injury, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to her injuries caused by Defendant's Allopurinol.

118. The Defendant owed a duty toward foreseeable users of ALLOPURINOL including

the Plaintiff, to exercise reasonable care to ensure that the ALLOPURINOL it manufactured and/or distributed were reasonably safe for ordinary and intended uses, and specifically, *inter alia*, to ensure through adequate testing, labeling, and otherwise, that physicians who would be likely to prescribe the products for their patients' use were adequately informed as to the potential effects of using the products in ordinary and foreseeable ways, in particular the risks of a severe skin reaction, SJS and/or TENS, inherent in such use.

119. Defendant failed to exercise reasonable care in testing ALLOPURINOL for side effects in ordinary and foreseeable users; and failed to disseminate to physicians information concerning the effects of ALLOPURINOL which was accurate, not misleading, and otherwise adequate to enable physicians to make informed choices concerning the use of ALLOPURINOL.

120. Defendant failed to exercise ordinary care in the manufacture, sale, testing, marketing, quality, assurance, quality control and/or distribution of the drug into the stream of interstate commerce in that Defendant knew or should have known that ALLOPURINOL created a foreseeable high risk of unreasonable, dangerous side effects and health hazards.

121. The dangerous propensities of ALLOPURINOL, as referenced above, were known or scientifically knowable, through appropriate research and testing, to the Defendant at the time it distributed, supplied, or sold the products, and not known to ordinary physicians who would be expected to prescribe the drug for Plaintiff and other patients, similarly situated.

122. The information the Defendant disseminated to physicians concerning

ALLOPURINOL was, in fact, inaccurate, misleading, and otherwise inadequate, as described above.

123. As a proximate result, Plaintiff suffered grievous bodily injuries and consequent economic and other losses when Plaintiff ingested, as prescribed, ALLOPURINOL, which had been developed, manufactured, labeled, marketed, distributed, promoted and/or sold, either directly or indirectly, by Defendant through third parties or related entities.

124. The Defendant was negligent, and breached duties owed to Plaintiff with respect to ALLOPURINOL in one or more of the following respects:

(a) Despite knowledge of hazards and knowledge that the product was frequently prescribed for the use, Defendant failed to accompany the product with adequate warnings and instructions regarding the adverse and long lasting side effects associated with the use of ALLOPURINOL;

(b) Defendant failed to conduct adequate testing;

(c) Despite knowledge of hazards, Defendant failed to conduct adequate post-marketing surveillance to determine the safety of the product;

(d) Despite knowledge of hazards, they failed to adequately warn Plaintiff physicians or Plaintiff that the use of ALLOPURINOL could result in severe side effects including but not limited to cutaneous events including but not limited to as SJS and/or TENS; and

(e) Despite the fact that the Defendant knew or should have known that ALLOPURINOL caused unreasonably dangerous side effects, Defendant failed to adequately disclose the known or knowable risks associated with ALLOPURINOL as set forth above; Defendant willfully and deliberately failed to adequately disclose these risks, and in doing so, acted with a conscious disregard of Plaintiff safety or welfare.

125. As a result of the negligence of the Defendant, ALLOPURINOL was prescribed to Plaintiff for the use and was used by the Plaintiff, thereby causing Plaintiff to sustain reasonably foreseeable serious and permanent damages and injuries as alleged in this

Complaint.

126. The negligence of the Defendant was a proximate cause of Plaintiff's harm and injuries that Plaintiff has suffered and will continue to suffer as previously described.

127. In the alternative, Defendant's acts of omissions and concealment of material facts of the design and manufacturing defects were made with the understanding that patients and physicians would rely upon such statements when choosing Defendant's ALLOPURINOL drug. Furthermore, the economic damages and physical harm caused by Defendant's conduct would not have occurred had Defendant exercised the high degree of care imposed upon it and Plaintiff therefore pleads the doctrine of *res ipsa loquitur*.

WHEREFORE, Plaintiff prays for judgment against Defendant, in an amount, which will compensate the Plaintiff for her injuries.

COUNT 3

MISREPRESENTATION BY OMISSION

128. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

129. Defendant misrepresented the soundness and reliability of ALLOPURINOL to physicians and the general public through promotional and marketing campaigns. It misrepresented that ALLOPURINOL was safe and/or effective when used as instructed, when, in fact, it was dangerous to the health of patients. Defendant continued these misrepresentations for an extended period of time, without disclosing material information.

130. Defendant took advantage of the limited opportunity Plaintiff had to discover Defendant strategic and intentional concealment of the design, manufacturing and safety defects in ALLOPURINOL.

131. At the time Defendant promoted the drug at issue as safe and/or effective, Defendant did not have adequate proof upon which to base such representations, and in fact, knew or should have known that drug was dangerous.

132. Defendant concealed these design and manufacturing defects from the public by withholding information pertaining to the inherent design, manufacturing and safety defects and high risks of a severe side effects as described herein, including SJS and/or TENS associated with Defendant's ALLOPURINOL drug and, instead presented ALLOPURINOL as safe and reliable.

133. Defendant's intentional misrepresentations and omissions were to the Plaintiff to induce purchase of Defendant's ALLOPURINOL drug over other safer alternative drugs on the market.

134. Defendant knew or should have known of the high risk Plaintiff would encounter by unwittingly agreeing to ingest Defendant's defective drug.

135. Defendant failed to exercise reasonable care and competence in obtaining and/or communicating information regarding the safe use of ALLOPURINOL and otherwise failed to exercise reasonable care in transmitting information to Plaintiff, Plaintiff's physician, and the public in general.

136. Defendant made the aforesaid representations in the course of Defendant business as designers, manufacturers, and distributors of ALLOPURINOL despite having no reasonable basis for their assertion that these representations were true and/or

without having accurate or sufficient information concerning the aforesaid representations. Defendant was aware that, without such information, it could not accurately make the aforesaid representations.

137. At the time the aforesaid representations were made, Defendant induced Plaintiff and/or Plaintiff's physicians to rely upon such representations.

138. Plaintiff and/or Plaintiff's physicians, at the time the representations were made, were unaware of their falsity and believed them to be true. In reasonable reliance thereon by Plaintiff and/or Plaintiff's physicians used ALLOPURINOL, and as a result, Plaintiff has suffered, and will continue to suffer, injury, harm and economic loss alleged herein.

139. As a direct and proximate result of reliance upon Defendant misrepresentations, Plaintiff has suffered and will continue to suffer injuries, harm, and economic loss as alleged herein, including a permanent and substantial physical disability, and expenses attributable to this disability.

WHEREFORE, Plaintiff prays for judgment against Defendant, in an amount, which will compensate the Plaintiff for her injuries.

COUNT 4

NEGLIGENCE PER SE

140. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

141. As set forth above, Defendant misrepresented to Plaintiff's physicians, and through them to Plaintiff and members of the general public, that ALLOPURINOL was safe

and that severe side effects as described herein including SJS and/or TENS were comparatively rare. These representations were, in fact, false. The true facts are that ALLOPURINOL is not safe and is in fact, dangerous to the health and body of Plaintiff, and others similarly situated.

142. Defendant made other representations about the safety and efficacy of ALLOPURINOL, and its minimal side effects all as set forth above and incorporated herein by reference.

143. ALLOPURINOL causes severe side effects as described herein including SJS and/or TENS far more frequently than represented, and Defendant did not disclose or warn physicians about the actual prevalence of known side effects of ALLOPURINOL.

144. Defendant misrepresented the safety of ALLOPURINOL and withheld warnings of the known side effects of ALLOPURINOL when used as commonly prescribed by physicians as specifically required by 21 C.F.R. § 201.128.

145. At the time Defendant made the above described representations, and at the time Plaintiff and Plaintiff physicians took the actions alleged in this Complaint, Plaintiff and Plaintiff's physicians were ignorant of the falsity of the representations and reasonably believed them to be true. In reliance upon the representations, Plaintiff's physicians were induced to and did prescribe ALLOPURINOL as described herein and Plaintiff did use ALLOPURINOL as described herein.

146. If Plaintiff's physicians had known the actual facts Plaintiff would not have been prescribed ALLOPURINOL and Plaintiff would not have taken ALLOPURINOL.

147. The reliance of Plaintiff and Plaintiff's physicians upon the representations of Defendant was justified because individuals and/or entities that appeared to be in the

position to know the true facts made the representations.

148. As a proximate result of the negligence of Defendant, Plaintiff sustained the injuries and damages described herein.

WHEREFORE, Plaintiff prays for judgment against Defendant, in an amount, which will compensate the Plaintiff for her injuries.

COUNT 5

NEGLIGENT MISREPRESENTATION

149. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

150. Defendant owed a duty to disseminate accurate and adequate information concerning ALLOPURINOL, and to exercise reasonable care to ensure that it did not, in those undertakings, create unreasonable risks of personal injury to others.

151. Defendant disseminated to physicians, through package inserts, and/or the publication of a PDR monograph, and/or otherwise mediums, information concerning the properties and effects of ALLOPURINOL, with the intention that physicians would rely upon that information when making a decision concerning whether to prescribe ALLOPURINOL for their patients.

152. Defendant as a drug manufacturer and/or distributor, knew or ought to have realized that the manufacturers and/or distributors of drug products, have a duty to ensure that the information contained in the package inserts accompanying their own prescription drug products is accurate, complete, not misleading, and otherwise

adequate, and to monitor medical literature and post marketing adverse events and to report any data affecting the safety of the drug to the appropriate agency and/or alert the medical community, Plaintiff's physicians, and through them, Plaintiff.

153. Defendant knew or ought to have realized, specifically, that physicians, in weighing the potential benefits and potential risks of using ALLOPURINOL and in writing prescriptions for "ALLOPURINOL," would rely upon information disseminated to them by the manufacturer of the drug product, regardless of whether the prescriptions might be filled with either the name brand product or generic ALLOPURINOL, and that many patients, in accordance with those prescriptions, would be likely to ingest Defendant's drug product.

154. Defendant knew or ought to have realized that patients receiving prescriptions for ALLOPURINOL written in reliance upon information they disseminated as the manufacturer/distributor of ALLOPURINOL would be placed in peril of grievous personal injury if the information thus disseminated and relied upon was materially inaccurate, misleading, or otherwise false.

155. Defendant failed to exercise reasonable care to ensure that the information they disseminated to physicians concerning the properties and effects of ALLOPURINOL was accurate and not misleading, and as a result disseminated information to physicians that was negligently and materially inaccurate, misleading, and false.

156. As a proximate and foreseeable result of this negligence on the part of Defendant the Plaintiff suffered grievous bodily injury and consequent economic and other loss, as described above, when Plaintiff's physician, in reasonable reliance upon the

negligently inaccurate, misleading, and false information disseminated by Defendant, and believing the information to be true, prescribed for the Plaintiff the use of ALLOPURINOL and Plaintiff ingested, per those prescriptions, ALLOPURINOL, leading to Plaintiff's injuries.

WHEREFORE, Plaintiff prays for judgment against Defendant, in an amount, which will compensate the Plaintiff for her injuries.

COUNT 6

BREACH OF IMPLIED WARRANTY

157. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

158. Defendant manufactured, marketed, sold, and distributed ALLOPURINOL.

159. At the time Defendant marketed, sold, and distributed ALLOPURINOL for use by Plaintiff, Defendant knew of the purpose for which ALLOPURINOL was intended and impliedly warranted ALLOPURINOL to be of merchantable quality and safe and fit for such use.

160. Plaintiff and her prescribing physician reasonably relied on the skill, superior knowledge, and judgment of Defendant as to whether ALLOPURINOL was of merchantable quality and safe and fit for its intended use.

161. Plaintiff used Defendant's product ALLOPURINOL which was provided to Plaintiff's prescribing physician by Defendant. Due to Defendant's wrongful conduct as alleged herein, Plaintiff could not have known about the risks and side effects associated with ALLOPURINOL until after Plaintiff ingested it.

162. Contrary to such implied warranty, Defendant's product ALLOPURINOL was not of merchantable quality and was not safe or fit for its intended use.

163. As a direct and proximate result of Defendant's breach of implied warranty, Plaintiff has suffered, and will continue to suffer injury and harm as previously alleged herein, including extreme pain and suffering. Loss of enjoyment of life, ascertainable economic loss, including the purchase price of ALLOPURINOL, out-pocket costs of medical tests and treatment, future medical care and/or services, and other costs incidental to Plaintiff's ingestion of harmful and defective products.

164. Defendant's aforementioned conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages in an amount to be determined at trial that is appropriate to punish Defendant and deter them from similar conduct in the future.

COUNT 7

BREACH OF EXPRESS WARRANTY

165. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

166. Defendant expressly warranted that ALLOPURINOL was safe and well accepted by patients and was safe for long-term use.

167. ALLOPURINOL does not conform to these express representations because ALLOPURINOL is not safe and has high levels of serious, life-threatening side effects.

168. As a direct and proximate result of the breach of said warranties, plaintiff has been damaged, and is therefore entitled to damages as described herein.

COUNT 8

WRONGFUL DEATH

169. Plaintiff repeats, reiterates, and re-alleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

170. At all times material hereto, Defendant owed a duty to Plaintiff to protect him against reasonably foreseeable harms which a prudent person would anticipate were likely to result from the Defendant acts or omissions.

171. Defendant breached that duty when they acted in the negligent and/or tortious manner set forth in Paragraphs above.

172. Defendant negligent and tortious conduct was the direct and proximate cause of Plaintiff, Catherine Webb's, pain and suffering leading up to her death.

173. If death had not ensued, Plaintiff would have been entitled to maintain a cause of action and recover damages against Defendant because of the above alleged negligent and tortious conduct.

174. As a direct, foreseeable and proximate result of Defendant's conduct, Plaintiff has incurred medical and funeral expenses.

175. As a direct, foreseeable and proximate result of the Defendant's conduct, Plaintiff's estate has been deprived of prospective net accumulations and loss of earnings.

WHEREFORE, Plaintiffs demand judgment for damages against Defendant for

an amount in excess of $75,000.00, together with interest, costs and attorneys fees, including but not limited to those damages provided pursuant to applicable Federal law, including but not limited to:

1. The value of lost support and services from the date of the Catherine Webb's injury to her death, with interest, and future loss of support and services from the date of death and reduced to present value;

2. Medical or funeral expenses due to the decedent's injury or death may be recovered;

3. As to Denise McLeod, as Personal Representative of the Estate of Catherine Webb: loss of earnings of the deceased from the date of injury to the date of death, less lost support of survivors excluding contributions in kind, with interest; loss of the prospective net accumulations of an estate, which might reasonably have been expected but for the wrongful death; and

4. Medical or funeral expenses due to the decedent's injury or death that have become a charge against Catherine Webb's estate.

5. All damages available to Catherine Webb's heirs and/or beneficiaries.

6. All damages arising from any and all survival claims.

V.

DEMAND FOR JURY TRIAL

176. Plaintiff hereby demands a trial by jury as to all issues so triable.

Respectfully Submitted,

BY: /s/ Lawrence Egerton, Jr.

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